REMARKS

Applicants would like to thank the Office for the substantive review given to this case. In the non-final Office Action, the Office rejected claims 1-42 and 51-54. More specifically:

- Claims 1-42 and 51-54 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter;
- Claim 1, 29, 30 and 51-54 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention;
- Claims 1, 7-21, 23-25, 29-36 and 51-53 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0042725 (Mayaud) in view of U.S. Patent Application Publication No. 2004/0049506 (Ghouri) and Applicants' Own Admission (AOA);
- Claims 2-6, 26, 27, 41 and 54 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mayaud in view of Ghouri, AOA and U.S. Patent No. 6,438,407 to Ousdigian et al. (Ousdigian);
- Claims 22, 28 and 37-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mayaud in view of Ghouri, AOA and Official Notice;
- Claim 42 is rejected under 35 U.S.C. §103(a) as being unpatentable over Mayaud in view of Ghouri, AOA, Ousdigian and Official Notice.

Claims 51, 52 and 54 have been cancelled without prejudice, and claims 1, 7-10, 13, 14, 29, 30 and 53 have been amended. Support for the amendments to claims 1 and 53 may be found throughout the specification, including at least paragraph [0049]. Claims 1 and 53 have also been amended to address the rejections under 35 U.S.C. §101. Furthermore, claims 1, 7-9, 13, 14, 29, 30 and 53 have been amended to address the rejections under 35 U.S.C. §112. Claim 10 has been amended to correct a typographical error. No new matter has been added as a result of these amendments.

Upon entry of this Preliminary Amendment, claims 1-42 and 53 will remain pending. For the reasons set forth hereinbelow, Applicants request that the rejections associated with the pending claims be withdrawn.

Rejections under 35 U.S.C. §101

The Office rejected claims 1-42 and 51-54 under 35 U.S.C. §101 as being directed to non-statutory subject matter. The cancellation of claims 51, 52 and 54 has rendered this rejection moot with respect to such claims.

Applicants respectfully submit that claims 1-42 and 53 satisfy 35 U.S.C. §101 under the "machine-or-transformation test" as recently clarified by the U.S. Court of Appeals in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), because the claims are tied to a particular machine for meaningful and significant claim activity. In particular, claim 1 previously stated that numerous limitations were performed by a processor. With respect to claims 52 and 53, the Office stated that the use of the term "processor," under the broadest reasonable interpretation, is hardware. *See* Office Action at 4-5. Accordingly, the term "processor" as used in claim 1 should similarly apply to hardware. Because hardware is a machine within the definition of 35 U.S.C. §101, claim 1 should be deemed patentable subject matter without amendment. However, in order to more explicitly identify that numerous limitations of claim 1 are performed by a machine, Applicants have amended claim 1 to state that such limitations are performed by a "processing device." Accordingly, Applicants submit that claims 1-42 represent patentable subject matter within the meaning of 35 U.S.C. §101 and as set forth in *In re Bilski* and respectfully request that the rejections of claims 1-42 under 35 U.S.C. §101 be withdrawn.

With respect to claim 53, the Office states that "'processor' and 'media' claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical 'things.' They are neither computer components nor statutory processes, as they are not 'acts' being performed." *See* Office Action at 5 (citing MPEP §2106.01(I)). Applicants respectfully traverse this rejection.

In particular, the cited portion of MPEP §2106.01(I) is not the most appropriate portion of such section with respect to the language of claim 53. Indeed, the paragraph of MPEP §2106.01(I) cited by the Office states, in full:

> Similarly, computer programs claimed as computer listings *per se*, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. *See In re Lowry*, 32 F.3d

> 1583-84, 32 USPQ2d at 1035. Accordingly, it is important to distinguish between claims that define descriptive material *per se* from claims that define statutory inventions. (underlining added)

In claim 53, the computer-readable medium, which is properly identified by the Office as hardware (*see* Office Action at 5), is encoded with programming instructions (i.e., a computer program). Such a computer-readable medium encoded with programming instructions constitutes a computer element that defines structural and functional interrelationships between the computer program and the rest of the computer, as set forth by *In re Lowry* and as cited in MPEP §2106.01(I). As such, claim 53 represents statutory subject matter.

In addition, Applicants have amended claim 53 in the same manner as claim 1 to more explicitly identify that the "processing device" is also hardware and a computer element, as such term is described in *In re Lowry* and MPEP §2106.01(I). For at least these reasons, Applicants respectfully request that the rejection of claim 53 under 35 U.S.C. §101 be withdrawn.

Rejections under 35 U.S.C. §112, ¶ 2

The Office has rejected claims 1, 29, 30 and 51-54 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention for use of one or more of the terms "adverse events" and "adverse side effects." Applicants note that claims 7-9 also utilize the term "adverse events." As such, Applicants have amended claims 1, 7-9, 29, 30 and 53 to address this rejection. The cancellation of claims 51, 52 and 54 has rendered this rejection moot with respect to such claims.

The Office has further rejected claims 1, 29, 30 and 51-54 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention for use of the term "logical." Applicants note that claims 29 and 30 do not use the term "logical." However, claims 13 and 14 do use such term. Accordingly, claims 1, 13, 14 and 53 have been amended to address this rejection. The cancellation of claims 51, 52 and 54 has rendered this rejection moot with respect to such claims.

Finally, the Office has rejected claims 1 and 51-54 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention for use of the term "adequate." Claims 1 and 53

have been amended to address this rejection. The cancellation of claims 51, 52 and 54 has rendered this rejection moot with respect to such claims.

Claims 1-42

Amended independent claim 1 is nonobvious over Mayaud in view of Ghouri and Applicants' Own Admission (AOA) because the cited references, either alone or in combination, fail to teach or suggest each and every limitation of amended claim 1. More particularly, the combination of Mayaud, Ghouri and AOA fails to teach or suggest the combination of at least the following limitations of amended independent claim 1:

- identifying a medication use process associated with a pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product, wherein the medication use process comprises diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient;
- determining, by the processing device, whether the medication use process protects patients from experiencing the one or more side effects; and
- based on the determination, identifying potential failure modes where the medication use process does not protect patients from experiencing the one or more side effects and identifying one or more multiple redundant interventions for each failure mode.

Mayaud discloses a wirelessly deployable, electronic prescription creation system for physician use that captures a patient condition and treatment objective into a prescription and provides a patient record assembly with privacy controls, adverse indication review, and online access to drug information. *See* Mayaud at Abstract. Mayaud further describes a *condition selection* which identifies a patient condition and enables a drug to be selected for such condition by a physician. *See id.* at [0269]-[0270].

Ghouri discloses a system and method for electronic and algorithmic data mining of an individual physician's prescribing history to determine the approximate distribution of diseases within a practice population for optimizing pharmaceutical sales and marketing. *See* Ghouri at Abstract. Ghouri discloses *comparing* one drug against competitor drugs by determining drug-drug, drug-disease, and drug-allergy interactions for a plurality of drugs, and determining a safety score for each interaction based on the severity and an expected frequency of the interaction. *See id.* at [0084].

In contrast, amended independent claim 1 requires identifying a medication use process associated with a pharmaceutical product wherein the medication use process is implemented to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product. The medication use process includes diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient. In contrast, Mayaud merely discloses a prescribing operation based on a determined condition. Mayaud does not identify a medication use process as described in amended claim 1.

Ghouri does not overcome the deficiencies of Mayaud. Ghouri does not describe any medication use process. Ghouri is directed to determining drug interactions between competitor drugs to determine which drug has the least severe and/or least common side effects. Ghouri does not teach or suggest identifying a medication use process as described in claim 1.

Similarly, AOA (i.e., paragraphs [0002]-[0006] of Applicants' specification) does not overcome the deficiencies of Mayaud and Ghouri. AOA is not directed to describing a medication use process. Rather, AOA is directed to identifying risk management programs. AOA does not teach or suggest identifying a medication use process as described in claim 1.

Claim 1 further requires determining whether the medication use process protects patients from experiencing the one or more side effects and, based on the determination, identifying potential failure modes where the medication use process does not protect patients from experiencing the one or more side effects and identifying one or more multiple redundant interventions for each failure mode. The Office does not assert that either Mayaud or Ghouri teaches or suggests identifying potential failure modes where the medication use process does not protect patients from experiencing one or more side effects. This is at least because neither Mayaud nor Ghouri teaches identifying potential failure modes. Rather, the Office depends on paragraphs [0002]-[0006] of Applicants' specification for such limitation. However, these paragraphs of Applicants' specification do not teach or suggest identifying potential failure modes where a medication use process does not protect patients from experiencing one or more side effects and identifying one or more multiple redundant interventions for each failure mode. Such paragraphs merely teach risk management programs that have been used to assess risk in industries including manufacturing, environmental, food industries and aviation.

Furthermore, paragraphs [0002]-[0006] discuss (1) using a weighted analysis to address only the most undesirable adverse event and then identifying potential failures in a system which may lead to those events and (2) a Failure Mode Effect Analysis ("FMEA") process, which is an engineering technique that a variety of industries have adopted that utilizes a systematic approach of identifying all potential failures in a system and then determining potential effects of each failure. Nothing in these paragraphs teaches or suggests the use of such processes to identify failure modes related to a medication use process that is implemented to protect patients from a risk of experiencing one or more side effects associated with use of a pharmaceutical product. Rather, paragraphs [0002]-[0006] merely disclose (1) identifying all potential failures *in a system* or (2) identifying failure modes of only the most undesirable adverse events *in a system* where a risk protection measure has not yet been implemented. The paragraphs do not disclose identification of failure modes of a risk protection implementation *process*, such as the medication use process of claim 1. Moreover, nothing in these paragraphs teaches or suggests identifying multiple redundant interventions for each of the failure modes identified for the medication use process of claim 1.

In addition, on pages 10 and 11 of the Final Office Action dated December 7, 2009, the Office states:

> Applicants' limitation, in claim 1: *wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Beaulieu/Silva-Craig [sic.]. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
>
> Applicant's limitation in claim 1: *to evaluate the need to mitigate the effect of said failure modes*; is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Dempsey [sic.]. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants note that these bases for rejection are inapposite to method claims, which do not necessarily define structures. Rather, method claims define operations that are performed. Because no structure must be substantively defined by a method claim, the use of a "wherein" clause in a method claim is a limiting requirement on the operation with which it is associated. It is only in system claims that structural limitations must be defined when using a wherein clause. As such, each of these limitations listed above, as amended consistent with the mark-up included in the Amendments to the Claims section above, should be given patentable weight with respect to claim 1.

Therefore, for at least the reasons set forth hereinabove, Applicants submit that claim 1 is nonobvious over the combination of Mayaud, Ghouri and AOA because the cited references fail to teach or suggest each and every limitation of claim 1. Because claims 2-42 depend from and incorporate all of the limitations of claim 1, claims 2-42 are also nonobvious over the cited references. *See* MPEP §2143.03 (stating that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious). Accordingly, Applicants request that the rejections associated with claims 1-42 be withdrawn.

Claim 53

Amended independent claim 53 is nonobvious over Mayaud in view of Ghouri and Applicants' Own Admission (AOA) because the cited references, either alone or in combination, fail to teach or suggest each and every limitation of amended claim 53. More particularly, the combination of Mayaud, Ghouri and AOA fails to teach or suggest the combination of at least the following limitations of amended independent claim 53:

- identifying a medication use process associated with a pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product, wherein the medication use process comprises diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient;
- determining, by the processing device, whether the medication use process protects patients from experiencing the one or more side effects; and
- based on the determination, identifying potential failure modes where the medication use process does not protect patients from experiencing the one or more side effects and identifying one or more multiple redundant interventions for each failure mode.

For substantially the same reasons as set forth above in reference to claim 1, claim 53 is nonobvious over the combination of Mayaud, Ghouri and AOA because the cited references fail to teach or suggest each and every limitation of claim 53. Accordingly, Applicants respectfully request that the rejection associated with claim 53 be withdrawn.

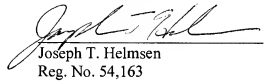
All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. There being no other rejections, Applicants respectfully request that the current application be allowed and passed to issue.

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, I invite the Examiner to telephone me directly.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this Preliminary Amendment, or credit any overpayment, to deposit account no. 50-0436.

Respectfully submitted,
PEPPER HAMILTON LLP



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